

***Remarks***

Claims 141-146, 148, 150-168, 170-175, 179, and 181-208 are pending in the present application. Claims 1-140, 147, 149, 169, 176-178, and 180 have previously been cancelled without prejudice or disclaimer. Claims 141, 154, 184, 187, 193-195, 198, 199 and 201-204 have been amended.

Claims 141, 154, 184, 187, 193-195, 198, 199 and 201-204 have been amended and claims 1-140, 147, 149, 169, 176-178, and 180 have been cancelled, to advance prosecution. Applicant's, by amending any claims herein and/or canceling any claims, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

Supervisory Examiner Krass is thanked for conducting an interview with the undersigned attorney on May 22, 2009. During the interview, Supervisory Examiner Krass indicated that the language "curing or preventing" should properly be amended to "treating." Further, Supervisory Examiner Krass stated that the term "including" as set forth in claims 198 and 202-204, should properly be amended to "comprising." Regarding the scope of enablement rejection under 35 USC § 112, Supervisory Examiner Krass stated that this rejection is inapplicable given the recitation of specific types of injuries/damage in the pending claims. In addition, Supervisory Examiner Krass indicated that upon filing the instant Amendment and amending the claims as suggested, a Patentability Conference would thereafter be held in this case.

Claims 141, 154, 184, 187 and 193-195 have been amended to replace the language “promoting healing or regeneration” with the term “treating.” Support for this amendment appears throughout the specification and claims as originally filed. No new matter has been added.

Claims 193, 198 and 202-204 have been amended to replace the term “including” with the term “comprising.” Support for this amendment appears throughout the specification and claims as originally filed. No new matter has been added.

In addition, claim 204 has been amended to replace the term “Intralipid®” with the phrase “a lipid mixture having 10% soybean oil, 1.2% egg phospholipids, and 2.2% glycerol.” Support for this amendment appears throughout the specification and claims as originally filed. No new matter has been added.

Lastly, claims 184, 193, 198, 199 and 201 have been amended to correct minor typographical errors. No new matter has been added.

In view of the remarks set forth herein, further and favorable consideration is respectfully requested.

***I. At page 2 of the Official Action, claim 204 has been rejected under 35 USC § 112, second paragraph.***

The Examiner asserts that claim 204 improperly recites the tradename “Intralipid®.”

In view of the following, this rejection is respectfully traversed.

Claim 204 has been amended to replace the term “Intralipid®” with the

phrase "a lipid mixture having 10% soybean oil, 1.2% egg phospholipids, and 2.2% glycerol."

In view of the foregoing, it is submitted that claim 204 is clear and definite within the meaning of 35 USC § 112, second paragraph. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

***II. At page 2 of the Official Action, claims 141-146, 148, 150-168, 170-175, 179 and 181-208 have been rejected under 35 USC § 112, second paragraph as being indefinite.***

The Examiner asserts that "It is unclear as to how a compound can regenerate different parts of the eye. The instant specification fails to show how the regeneration of all the cells and segments are done." In addition, the Examiner asserts, with regard to claims 193 and 202, that the term "including" is indefinite.

In view of the following, this rejection is respectfully traversed.

As discussed above and in accordance with the suggestions of Supervisory Examiner Krass, claims 141, 154, 184, 187 and 193-195 have been amended to replace the language "promoting healing or regeneration" with the term "treating." Additionally, claims 193, 198 and 202-204 have been amended to replace the term "including" with the term "comprising."

In view of the foregoing, it is submitted that claims 141-146, 148, 150-168, 170-175, 179 and 181-208 are clear and definite within the meaning of 35 USC § 112, second paragraph. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

**III. At page 3 of the Official Action, claims 141-146, 148, 150-168, 170-175, 179 and 181-208 have been rejected under 35 USC § 112, first paragraph as failing to comply with the written description requirement.**

The Examiner asserts that the “claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to ‘A method of promoting healing or regeneration of damaged eye epithelium or cornea or the anterior segment of the eye ...’ Such method is directed to the treatment of unspecified disorder and no evidence indicates that the treatable disease was known to the applicant. In the absence of understanding the disease to be treated, the artisan would not have accepted that applicant was in possession of the claimed invention.”

In view of the following, this rejection is respectfully traversed.

As discussed above and in accordance with the suggestions of Supervisory Examiner Krass, claims 141, 154, 184, 187 and 193-195 have been amended to replace the language “promoting healing or regeneration” with the term “treating.” Additionally, claims 193, 198 and 202-204 have been amended to replace the term “including” with the term “comprising.”

The test under 35 USC § 112, first paragraph, for determining compliance with the written description requirement is whether the application clearly conveys that an applicant has invented the subject matter which is claimed. *In re Barker*, 194 USPQ 470, 473 (CCPA 1977); **MPEP § 2163**. Also, the applicant

must convey to the public what the applicant claims as the invention so that the public may ascertain if the patent applicant claims anything in common use or already known. **MPEP § 2163**. Lastly, the specification must convey that the applicant was in possession of the invention. **MPEP § 2163**. The Examiner is respectfully reminded that the Examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *In re Wertheim*, 191USPQ 90, 98 (CCPA 1976).

In addition, Applicant notes that the United States Patent and Trademark Offices' "Revised Interim Written Description Guidelines Training Materials" states the following at page 4:

It is assumed at this point in the analysis that the specification has been reviewed and an appropriate search of the claimed subject matter has been conducted. It is also assumed that the examiner has identified which features of the claimed invention are conventional taking into account the body of existing prior art. There is a ***strong presumption that an adequate written description of the claimed invention is present in the specification as filed***. If the examiner determines that the application does not comply with the written description requirement, the ***examiner has the initial burden***, after a thorough reading and evaluation of the content of the application, of ***presenting evidence or reasons*** why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. It should also be noted that the test for an adequate written description is separate and distinct from the test under the enablement criteria of 35 U.S.C. § 112 first paragraph. ***The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. § 112 para. 1, for lack of adequate written description.*** (emphasis added)

See *also* page 6 of the Guidelines "Written Description Amended or New Claims...Decision Tree."

In the present case, the Examiner has provided ***no reasons or evidence*** as to why a person skilled in the art would not recognize that the written description of the invention provides support for the present claims. Rather, the Examiner simply states "In the absence of understanding the disease to be treated, the artisan would not have accepted that applicant was in possession of the claimed invention." Accordingly, the Examiner has ***not*** transferred the burden for establishing adequate written description.

Further, assuming *arguendo* that the initial burden has been met by the Examiner, the claims clearly recite particular disorders or conditions associated with eye epithelium, cornea or anterior segment damage, and the present specification clearly describes such disorders and conditions. In addition, Supervisory Examiner Krass during the Examiner interview held on May 22, 2009, acknowledged that such disorders and conditions were adequately described. Accordingly, if this rejection is to be maintained, the Examiner is requested to thoroughly and expressly address each argument presented herein including authority and the Interview Summary of record in this case.

It is submitted that the claims are described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, within the meaning of 35 USC § 112, first paragraph. Thus, the Examiner is respectfully requested to withdraw this rejection.

***IV. At page 3 of the Official Action, claim 154 has been rejected under 35 USC § 112, first paragraph as failing to meet the enablement requirement.***

The Examiner asserts that the “specification, while being enabling for treating corneal epithelium damage, does not reasonably provide enablement for preventing or curing damaged eye epithelium. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to ‘curing or prevention’ of the invention commensurate in scope with these claims.”

In view of the following, this rejection is respectfully traversed.

Claim 154 has been amended to replace the language “promoting healing or regeneration” with the term “treating.” Further, it is submitted that, regarding the scope of enablement rejection under 35 USC § 112, supervisory Examiner Krass stated that this rejection is inapplicable. Accordingly, Applicants submit that the present specification as well as the knowledge of one of ordinary skill in the art, fully enables the skilled artisan to make and use the full scope of the claimed subject matter within the meaning of 35 USC § 112, first paragraph.

In view of the foregoing, it is submitted that claim 154 is fully enabled within the meaning of 35 USC § 112, first paragraph. Thus, the Examiner is respectfully requested to withdraw this rejection.

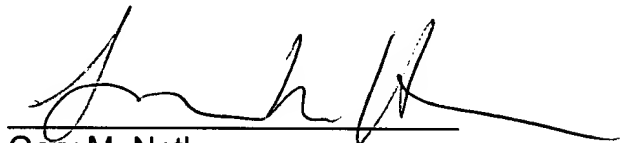
***Conclusion***

In view of the remarks set forth herein, Applicant submits that the pending claims are in condition for immediate allowance. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicant petitions for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

**THE NATH LAW GROUP**

A handwritten signature in black ink, appearing to read 'Gary M. Nath', is written over a horizontal line.

Gary M. Nath  
Registration No. 26,965  
Susanne M. Hopkins  
Registration No. 33,247  
Customer No. 20259

Date: May 26, 2009  
**THE NATH LAW GROUP**  
112 South West Street  
Alexandria, VA 22314  
Tel: (703) 548-6284  
Fax: (703) 683-8396